UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/206,852	12/08/98	ALLISON R	6550000028

HM12/0330

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EXAMINER	
GRUNBERG, A	
ART UNIT	**PAPER NUMBER**
1638	9

DATE MAILED: 03/30/00

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/206,852	Allison et al.
Examiner	**Group Art Unit**
Anne Marie Grunberg	1638

☒ Responsive to communication(s) filed on *Dec 21, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is clos d** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-16* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

The request filed on 21 December 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/206,852 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 4, 6-8, and 16 and dependant claims 2-3, 5, and 9-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgene that is part of a binary Ti plasmid vector introduced into a dicot seedling, does not reasonably provide enablement for any plasmid vector for any type of plant. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only provides guidance for transformation of a dicot using a transgene that is part of a binary Ti plasmid vector. In contrast, the claims are drawn to any type of DNA or DNA construct inserted into any type of plant using electrophoresis.

An, on the top of page 48, teaches that only the 25-bp border sequences located at each end of the T-DNA are required for the DNA transfer mechanism. At the bottom of page 48, An further teaches that binary Ti plasmid vectors were developed to facilitate handling.

Applicants effectively used a combination *Agrobacterium*/electrophoresis technique to overcome some of the problems associated with electrophoresis as detailed by Songstad et al on pages 9 and 10. At the bottom of page 9, Songstad et al teach that the resistance attributed to plant tissue can affect the rate of DNA migration. Under constant voltage, an increase in resistance will decrease the current and reduce DNA migration. Part of the resistance of plant tissue is due to the distance between the anode and the cathode. By placing the electrodes as close to each other as possible, a lower resistance is obtained.

The instant invention employs a seedling wherein the negative electrode is placed on the tip of the apical meristem and the positive electrode is placed near the root as is shown in figure 1. This large distance between the electrodes causes a large resistance which is not easily overcome by increasing the amperage due to tissue mortality rates.

It seems that in order to ensure penetration of the meristematic tissue and to prevent chimeras, the binary Ti plasmid vector is an essential element of the invention. As a result, since it is well known in the art that *Agrobacterium* infection is primarily limited to dicots, and absent any contradicting data, the invention as described in the specification would only be expected to operate with plants that are susceptible to *Agrobacterium* infection.

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate different transgene constructs without a binary Ti plasmid vector which would allow stable transformation of any plant not susceptible to *Agrobacterium* using electrophoresis.

Modification of the claims to include a binary Ti plasmid vector and limitation to *Agrobacterium* susceptible species would obviate this rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 4, 6, 9-11, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Songstad et al.

Claims 1-2, 4, 6, 9-11, 14, and 16 are drawn to a method of transforming a plant wherein the meristematic tissue of the plant is in contact with a medium comprising DNA and a negative lead from a power source and wherein the positive lead of the power source is in contact with an area below the meristematic tissue, and wherein a low amperage current from the power source causes the DNA to migrate from the medium to the cells of the meristematic tissue of the plant. The transformed plant may be a dicot, the DNA may be a plasmid vector, the current may be from 0.01 or 0.1 to about 0.5 or 1.0 mA, and the meristematic tissue may be from an apical meristem, a lateral meristem, or a meristematic dome. Additionally, the area of the plant below the meristematic tissue is a stem, and a transgenic plant is produced using electrophoresis.

Songstad et al teach transformation of an embryo using electrophoresis (pages 9-10). Songstad et al, on page 9 (column 2, 1st paragraph) refers to Ahokas who transformed a monocot embryo wherein the embryo was in contact with a medium comprising DNA and a negative lead of a power source wherein the medium containing the DNA punctured a barley embryo near its apical meristem (page 9, column 2, lines 1-5). The positive lead was in a medium that was in contact with a basal portion of the embryo (page 9, column 2, lines 5-7). A low amperage current of 0.1 mA was applied from the power source causing the DNA to migrate from the medium to the cells of the meristematic tissue of the plant (page 9, column 2, lines 7-12, lines 18-23, for example). Songstad further describes a typical current of 0.5 mA (page 10, column 1,

3rd full paragraph). Transformation of dicot embryos are taught on page 10 (column 1, 4th full paragraph), in addition to a plasmid vector pBI121. Transgenic orchids were confirmed through PCR analysis on 1 year old plants (page 10, column 1, last sentence in the fourth full paragraph).

5. Claims 1-2, 5-6, and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Burchi et al.

Claims 1-2, 5-6, and 9-16 are drawn to a method of transforming a plant using electrophoresis, such that a medium containing DNA and a negative lead to a power source is in contact with meristematic tissue, and a positive lead of a power source is contacting an area of the plant below the meristematic tissue, such that a low amperage current applied from the power source causes the DNA to migrate from the medium to the cells of the meristematic tissue of the plant. Additionally the plant may be a dicot, a seedling, the DNA a plasmid vector, and the meristematic tissue an apical meristem, a lateral meristem, or a meristematic dome. The current may range from about 0.01 to about 1.0 mA, or from about 0.1 to about 0.5 mA. The area of the plant below the meristematic tissue may be a root or a stem. Claim 16 is drawn to a transgenic plant produced by the electrophoresis of meristematic tissue. .

Burchi et al teach that DNA sequences can be introduced into intact meristems of germinating seeds, embryos, bulblets, axillary shoots and protocorms by electrophoresis (page 163, column 2, 2nd full paragraph). Burchi et al teach a medium containing DNA and a negative lead to a power source that is in contact with dome meristematic tissue of an axillary shoot (page

164, column 1, last paragraph), and a positive lead of a power source that is in contact with the soil, as close as possible to the roots which is an area of the plant below the meristematic tissue, (page 164, bottom of the last paragraph in the first column) such that a low amperage current applied from the power source (page 164, second column, first paragraph under "Results") causes the DNA to migrate from the medium to the cells of the meristematic tissue of the plant (page 165, figure 1; page 165, column 2, lines 6-15; page 166, column 1, lines 1-26, for example). The amperage ranges were 0.2, 0.5, and 1.0 mA (page 164, column 2, first paragraph under "Results"). The DNA is plasmid pBI-121 (page 164, column 1 under the heading "plasmids"). Burchi et al teach that dicots such as *carnation, chrysanthemum, lisianthus* (page 164, lines 1-3 under "Plant material), as well as cherries, orchids, beans, peppers, and red buds (page 166, bottom of column 1) have been transformed using the above method. Burchi et al also teach that treated shoots were being grown into whole plants to test for GUS activity (page 166, column 2, last paragraph).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burchi et al in view of Ahokas et al.

Claims 1-16 are drawn to a method of transforming a plant using electrophoresis, such that a medium containing DNA and a negative lead to a power source is in contact with meristematic tissue, and a positive lead of a power source is contacting an area of the plant below the meristematic tissue, such that a low amperage current applied from the power source causes the DNA to migrate from the medium to the cells of the meristematic tissue of the plant. Additionally the plant may be a seedling, the DNA a linearized plasmid vector containing a gene for barley oxalic acid oxidase, and the meristematic tissue an apical meristem, a lateral meristem,

or a meristematic dome. The current may range from about 0.01 to about 1.0 mA, or from about 0.1 to about 0.5 mA. The area of the plant below the meristematic tissue may be a root or a stem. Claim 16 is drawn to a transgenic plant produced by the electrophoresis of meristematic tissue.

Burchi et al teach that DNA sequences can be introduced into intact meristems of germinating seeds, embryos, bulblets, axillary shoots and protocorms by electrophoresis (page 163, column 2, 2nd full paragraph). Burchi et al teach a medium containing DNA and a negative lead to a power source which is in contact with dome meristematic tissue of an axillary shoot (page 164, column 1, last paragraph), and a positive lead of a power source which is in contact with the soil, as close as possible to the roots; an area of the plant below the meristematic tissue, (page 164, bottom of the last paragraph in the first column) such that a low amperage current applied from the power source (page 164, second column, first paragraph under "Results") causes the DNA to migrate from the medium to the cells of the meristematic tissue of the plant (page 165, figure 1; page 165, column 2, lines 6-15; page 166, column 1, lines 1-26, for example). The amperage ranged from 0.2, 0.5, and 1.0 mA (page 164, column 2, first paragraph under "Results"). The DNA is plasmid pBI-121 (page 164, column 1 under the heading "plasmids"). Burchi et al teach that dicots such as *carnation, chrysanthemum, lisianthus* (page 164, lines 1-3 under "Plant material), as well as cherries, orchids, beans, peppers, and red buds (page 166, bottom of column 1) have been transformed using the above method. Burchi et al also teach that treated shoots were being grown into whole plants to test for GUS activity (page 166, column 2, last paragraph).

Burchi et al do not teach a monocot plant, a soybean plant, a linearized plasmid vector, or a plasmid containing the gene for barley oxalic acid oxidase.

Ahokas teaches a monocot transformed by electrophoresis (abstract). On page 471 (column 2, lines 18-21), Ahokas teaches a linearized pB1221 DNA which was used for transformation purposes.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of transformation taught by Burchi et al to transform monocots such as barley as taught by Ahokas. It would have been obvious to transform soybean given the agronomic advantages of transformed soybean and given that several different species of dicots have been successfully transformed (Burchi et al, page 166, bottom of column 1). Any agronomically interesting gene such as barley oxalic acid oxidase which could have been inserted into a vector could be used to transform any plant type as described above. It would have been the optimization of process parameters to use linearized plasmid DNA.

Summary

No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Marie Grünberg whose telephone number is (703) 305-0805. The examiner can normally be reached Monday through Friday from 8:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

AMG

March 25, 2000